



the PRUDENT prescriber

Phil Mohler, M.D.

July 2023

In this edition:

- Routine Vitamin and Mineral Supplements: Nope! (pg. 1)
- Optimal stroke preventive strategy (pg. 1)
- Clostridium difficile Infection (CDI) (pg. 2)
- RSV vaccine approved for people ages >60 (pg. 2)
- Cochrane Weighs in (again) on Cranberries for Preventing Urinary Tract Infections (pg.3)
- OTC Naloxone Spray (pg.3)
- COVID Vaccine Update (pg. 3)

Routine Vitamin and Mineral Supplements: Nope!

The Vitamin Cottage and GNC are cringing and thankful that most of the general population does not follow the pronouncements of the US Preventive Services Task Force. (USPSTF) In an update of their 2014 recommendations, the USPSTF, based on 50 new studies, continues to recommend:

- There is no benefit and likely harm from use of beta-carotene. Increased risk of lung cancer. (**D** recommendation = Do not do)
- Lack of either benefit or harm from use of vitamin E. (**D** recommendation = Do not do)
- They found insufficient evidence to make a recommendation for or against the use of multivitamins or other nutrients (except beta-carotene and vitamin E) for preventing cardiovascular disease or cancer. (**I** statement = not enough evidence to make a decision)



MY TAKE



Having lived with a registered dietitian for over five decades, I am unabashedly anti-vitamin/mineral supplements in community-dwelling, non-pregnant adults who have no known nutritional deficiencies. In the face of over half of all American adults taking a vitamin and/or mineral supplement, this is an uphill battle. It may be prudent to concentrate on discouraging beta-carotene and vitamin E.

Optimal stroke preventive strategy for patients with atrial fibrillation in those 80 years and older, and in those with cognitive impairment and dementia

- In a meta-analysis of 53 studies that included patients over 80 years with atrial fibrillation, novel oral anticoagulants had better outcomes than vitamin K antagonists or no oral anticoagulant therapy regarding efficacy and safety profiles. The authors suggest that edoxaban (Savaysa \$400/mo.) and apixaban (Eliquis \$519/mo.) may be preferred

treatment options as they were safer than other anti-thrombotic strategies. [[Age Aging 2022 Dec 5;51\(12\)](#)]

- In a study ([J Am Geriatr Soc 2023 Feb.71:394](#)) where 1200 older adults with atrial fibrillation (mean age, 75) were followed for two years, anticoagulation was associated with increased major bleeding or death in cognitively impaired patients, but not in cognitively intact patients. In the cognitively impaired group, the number needed to treat (NNT) for stroke prevention was 30. The number needed to harm (NNH) with use of anticoagulation was 8.
- In a study of 15,000 nursing home residents with atrial fibrillation and advanced dementia, anticoagulation was associated with significantly more episodes of serious bleeding. However, the stroke risk was not decreased. Patients who received anticoagulation lived about 2.5 months longer on average. ([J Am Geriatr Soc 2023 February; 71:561](#))



To summarize: Over 75-80 years old and cognitively intact with atrial fibrillation, prescribe one of the novel oral anticoagulants, if your patient is affluent. Do not anticoagulate elderly cognitively impaired patients with atrial fibrillation.

Clostridium difficile Infection (CDI): Changing Treatment Approaches

Two studies caught my eye regarding management of recurrent CDI. The first was a small (42 patients) Danish study that randomized patients with one or two episodes of CDI who had just completed oral vancomycin therapy to either fecal microbiota transplantation (FMT) or placebo. The trial was stopped after an analysis showed 90% of the FMT recipients had CDI resolution in eight weeks compared to 33% of placebo recipients. ([Lancet Gastroenter Hepatol 2022 Dec 7:1062](#))

The second study ([JAMA 2023 April 15](#)) treated adults at high risk for recurrence of CDI with VE303 (a novel oral microbiome, directed therapy composed of non-pathogenic, non-toxic commensal strains of clostridia). Through week eight, the CDI recurrence rate was 13.8 % for the high-dose VE303 group and 45.5% for the placebo group. (NNT = 3.2)



I'm not sure where either of these studies will pan out, but the movement away from repeated ineffectual courses of antibiotics for recurrent CDI seems clear.

RSV vaccine approved for people ages >60

In an ongoing three-year double blind multi-national RCT, 25,000 adults over age 60 were given Arevxy, a recombinant stabilized protein subunit IM vaccine or IM placebo. After the first of three trial seasons:

- 7 of the 12,466 vaccine patients developed laboratory proven RSV.
- 39 of the 12,494 placebo patients developed laboratory proven RSV.
- Number needed to immunize (NNI) to prevent one case of RSV in one season = 400.

- Common adverse effects included fatigue, muscle aching and headaches. Ten people who received the vaccine and four who did not reported atrial fibrillation within 30 days.



- I was unaware that RSV is responsible for between 60,000 and 120,000 hospitalizations and between 6000 and 10,000 deaths each year in the US in adults aged 65 years or older. (CDC)
- In terms of vaccine efficacy, a NNI of 400 is reasonable efficacy.
- I'm going to sit tight to watch the outcomes through a second respiratory season.
- In the face of significant vaccine hesitancy in our country, it's probably a lousy time to introduce a new vaccine.

Cochrane Weighs in (again) on Cranberries for Preventing Urinary Tract Infections

- In their fifth update on the subject since 1998, the Cochrane Database Systemic Review, 2023 April 17; 4(4) added 26 new studies (now 50 studies with a total of 8857 randomized participants) asking the question: "Do cranberries prevent urinary tract infections?"
- These data support the use of cranberry products to reduce the risk of symptomatic urinary tract infections in women with recurrent UTIs, in children, and in people susceptible to UTI following interventions.
- The current evidence does not support using cranberry products in the elderly, in institutionalized patients, in patients with problems emptying their bladders or in pregnant women.

OTC Naloxone Spray

On March 29, 2023, the U.S. Food and Drug Administration approved Narcan, 4 milligram (mg) naloxone hydrochloride nasal spray for over-the-counter use. This is the first naloxone product approved for use without a prescription. The FDA touts that this product will now be widely available in grocery stores, convenience stores, and gas stations as well as online. The FDA Commissioner Dr. Robert Califf in patting himself on the back, *"Today's approval of OTC naloxone nasal spray will help improve access to naloxone, increase the number of locations where it's available and help reduce opioid overdose deaths throughout the country. We encourage the manufacturer to make accessibility to the product a priority by making it available as soon as possible and at an affordable price."*



This is a move in the right direction and will hopefully push other generic manufactures of Naloxone to get into the OTC market. The obvious barriers are price (\$35 - \$65) the stigma of purchase (think condoms) and just how available the new OTC product will be. The OTC product is packaged in a large box and will likely end up behind the counter in many businesses.

Covid Vaccine Update

This fall's Covid-19 vaccines will target Omicron subvariant XBB.1.5. On June 15, 2023, members of the FDA Vaccine and Related Biological Products Advisory Committee (VRBPAC) voted unanimously to recommend updating the COVID-19 vaccine composition to a monovalent XBB lineage. The CDC's Advisory Committee on Immunization Practices will meet soon to decide who should get the new vaccine and when.

Looking for previous versions of the Prudent Prescriber newsletter? Good news, 10 YEARS of monthly editions are now available on rmhp.org.

Prudent Prescriber
Authored by Phil Mohler, MD



Sponsored by Rocky Mountain Health Foundation



Distributed by Rocky Mountain Health Plans (RMHP),
a UnitedHealthcare Company (UHC)

Opinions and content are not endorsed by UHC or RMHP

